



## Benign Prostatic Hyperplasia (BPH) Treatments

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<b>State(s):</b> <input checked="" type="checkbox"/> Idaho <input checked="" type="checkbox"/> Montana <input checked="" type="checkbox"/> Oregon <input checked="" type="checkbox"/> Washington <input type="checkbox"/> Other:	<b>LOB(s):</b> <input checked="" type="checkbox"/> Commercial <input checked="" type="checkbox"/> Medicare <input checked="" type="checkbox"/> Medicaid
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### Enterprise Policy

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*Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determination are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.*

### Background

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Benign Prostatic Hyperplasia (BPH), is a noncancerous increase in size of the prostate gland. The enlarged prostate gland presses against the urethra. BPH can lead to symptoms like frequent urination, trouble starting to urinate, weak stream, inability to urinate, or loss of bladder control. BPH is treated with lifestyle changes, medication, and surgery (transurethral resection of the prostate (TURP). Alternative available treatment options include the prostatic urethral lift (PUL), the Rezum system, and AquaBeam® system.

The prostatic urethral lift (PUL) procedure is used to treat the symptoms of benign prostatic hyperplasia (BPH). The prostatic urethral lift procedure involves placement of 1 or more implants in the lateral lobes of the prostate using a transurethral delivery device. The implant (s) separate enlarged prostate lobes to reduce pressure on the urethra to allow for an easier urine flow.

The Rezum System procedure is a transurethral treatment for benign prostatic hyperplasia (BPH). This procedure is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with benign prostrate hyperplasia (BPH).The Rezum System utilizes convective radiofrequency water vapor energy to ablate the hyperplastic tissue of the prostate.

The AquaBeam® System (waterjet tissue ablation) is a minimally invasive medical device that is controlled with electromechanical precision and live ultrasound which delivers a high-velocity saline stream tissue to ablate prostatic glandular tissue without the production of heat. The AquaBeam® system consists of three components: a single-use probe, a robotic hand piece, and a console. The AquaBeam® probe is attached to the hand piece and inserted in the urethra; cystoscopic visualization is available continuously during the procedure. After mapping the desired tissue to be ablated, high-velocity sterile saline is delivered to the prostate tissue via the AquaBeam probe, which also provides a channel for aspiration of ablated tissue during the procedure. After excision of tissue from the prostate,

the jet's pressure is reduced so that it can be used to carry a laser light beam to cauterize the excised area. The aim is to reduce the heat damage to adjacent tissue that is commonly seen in other available interventions.

## Criteria

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### Commercial

**Prior authorization is required.**

#### I. Prostatic Urethral Lift

PacificSource considers prostatic urethral lift (PUL), using an FDA approved device, for the treatment of lower urinary tract symptoms (LUTS) due to BPH to be medically necessary when **ALL** of the following criteria are met:

1. Age 45 years or older;
2. Prostate volume no greater than 100cc based on ultrasound imaging;
3. No obstructive median lobe of the prostate identified on cystoscopy;
4. Peak flow rate (Qmax) is less than or equal to 12mL/second;
5. Intolerance, contraindication, or failure of medications (3 month trial) for treatment of BPH symptoms (e.g., alpha blockers, PDE5 Inhibitor, finasteride, dutasteride);
6. Lower urinary tract symptoms, to include:
  - a. urinary frequency;
  - b. urgency;
  - c. nocturia;
  - d. weak stream;
  - e. straining; and/or
  - f. intermittency.
  
7. Free from contraindications, including the following:
  - a. active urinary tract infection;
  - b. urinary incontinence; or
  - c. gross hematuria.

#### II. Rezum System - Transurethral Water Vapor Therapy

PacificSource considers the transurethral water vapor therapy procedure (e.g. Rezum system procedure), for lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH) medically necessary when **ALL** the following criteria have been met:

One treatment for LUTS/BPH is covered in patients with **BOTH** of the following:

1. Indications Including **ALL** of the following;
  - a. Age greater than or equal to 50;
  - b. Symptomatic despite maximal medical management including **ALL** of the following:
    - International Prostate Symptom Score (IPSS)  $\geq 13$ ;

- Maximum urinary flow rate (Qmax) of  $\leq 15$  mL/s (voided volume no greater than 125 cc);
  - Failure, contraindication or intolerance to at least three months of conventional medical therapy for BPH (e.g., alpha adrenergic blockers, PDE5 Inhibitor, finasteride, dutasteride);
- c. Prostate gland volume is estimated to be  $\geq 30$  to  $\leq 100$  cc, by clinical or ultrasound assessment.

**2. No contraindications including **any** of the following;**

- a. Known or suspected prostate cancer (based on NCCN Prostate Cancer Early Detection guidelines) or a prostate specific antigen (PSA)  $> 10$  ng/mL;
- b. Active urinary tract infection;
- c. History of bacterial prostatitis in the past three months;
- d. Prior prostate surgery;
- e. Neurogenic bladder; or
- f. Active urethral stricture (e.g., the source of the current LUTS).

**III. AquaBeam® System (waterjet tissue ablation)**

PacificSource considers AquaBeam® System medically necessary for treatment of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) when **ALL** of the following criteria is met:

1. Prostate gland volume is less than or equal to 80 mL based on ultrasound imaging;
2. International Prostate System Score (PPSS) is greater than or equal to 13;
3. No active urinary tract infection;
4. Conservative management options (e.g.,  $\alpha_1$ -adrenergic antagonists, 5 $\alpha$ -reductase inhibitors, or combination medication therapy) of at least three months have been unsuccessful;
5. Surgical intervention is indicated.

**Medicaid**

PacificSource Community Solutions (PCS) follows Guideline Note 145 of the OHP Prioritized List of Health Services for coverage of Prostatic Urethral Lift.

PacificSource Community Solutions (PCS) follows Guideline Note 173 of the OHP Prioritized List of Health Services and considers treatment Insufficient Evidence of Effectiveness for Rezum System – Transurethral Water Vapor Therapy.

**Medicare**

PacificSource Medicare follows CMS guidelines and criteria. In the absence of internal policy guidelines, CMS criteria, and evidence-based criteria, requests are reviewed on an individual basis for determination of coverage and medical necessity.

PacificSource Medicare follows Local Coverage Determination L37808 for Water Vapor Therapy for LUTS/BPH.

## Experimental/Investigational/Unproven

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PacificSource considers the use of temporary removable or biodegradable prostatic urethral stents to be experimental, investigational and unproven.

PacificSource considers Prostate Arterial Embolization (PAE) (Transcatheter Embolization, CPT 37242, 37243) for treatment of Benign Prostate Hyperplasia to be experimental, investigational and unproven.

PacificSource considers the use of AquaBeam® System (waterjet tissue ablation) to be experimental, investigation, unproven for any other indication than listed above.

## Coding Information

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The following list of codes are for informational purposes only and may not be all-inclusive.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

- 0421T Transurethral waterjet ablation prostate control post-op bleeding including US guide/complete(vasect/meatotomy/cystourethro/urethral calibration/dilation & internal urethrot)
- 0582T Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance
- 37242 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary
- 37243 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary
- 52441 Cystourethroscopy with transurethral resection or incision of ejaculatory ducts
- 52442 Each additional permanent adjustable transprostatic implant.
- 53854 Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy
- 53899 Unlisted procedure code, male genital system
- C2596 Probe, image guided, robotic, waterjet ablation
- C9739 Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
- C9740 Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants

CPT® codes, descriptions and materials are copyrighted by the American Medical Association (AMA).

HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS).

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## Appendix

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**Policy Number:**

**Effective:** 12/31/2020

**Next review:** 4/1/2022

**Policy type:** Enterprise

**Author(s):**

**Depts:** Health Services

**Applicable regulation(s):** [Applicable Regulations(s)]

**Commercial Ops:** 12/2021

**Government Ops:** 12/2021